UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,930	10/11/2001	Michael Poirier	560.09-US1	4572

34284 7590 03/31/2005

ROBERT D. FISH
RUTAN & TUCKER LLP
611 ANTON BLVD 14TH FLOOR
COSTA MESA, CA 92626-1931

EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/977,930	POIRIER ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *December 20, 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pourahmadi et al., 6,440,725, in view of Nelson et al., 6,074,827.

Pourahmadi et al. discloses the invention substantially as claimed, except for the magnetic beads carrying an affinity marker that binds a target antigen.

More specifically, Pourahmadi et al. discloses a container having at least one flexible sheet (column 22, line 13), a fluid receiving port (column 9, lines 52-59), a fluid discharge port (column 9, lines 52-59), and a plurality of compartments (127 and 141) fluidly coupled to at least one of the fluid receiving port and the fluid discharge port (col. 9, lines 52-59); wherein the fluid port is configured to receive a continuous flow of a biological fluid, and wherein the fluid discharge port is capable of emitting a continuous flow of the biological fluid that is at least partially depleted from a target antigen (column 9, lines 52-59, disclosing elution fluid into chamber 127; column 18, lines 40-45) while the fluid receiving port receives the continuous flow of the biological fluid; wherein at least one of the compartments further comprises a plurality of magnetic beads (column 18, line 43); and wherein the target antigen is capable of being separated from the

biological fluid using a magnetic force and an automatic mechanical force (column 18, lines 42-50; and column 22, lines 11-14), wherein at least one of the magnetic force and automatic mechanical force is transmitted through the flexible sheet (column 22, lines 11-14).

As to claim 2, at least one of the compartments includes a buffer fluid (column 10, line 2).

As to claim 4, at least one of the compartments further includes a port that allows draining of the at least one of the compartments (column 9, line 52-59).

As to claim 5, the biological fluid comprises whole blood (column 5, line 54).

As to claim 6, the target antigen is present on a bacterium (column 2, line 5).

The Pourahmadi et al. microfluidic device is used for separating a desired analyte from a fluid sample (col. 2, lines 37-39), and utilizes beads in a channel or chamber in the microfluidid device as a solid support for capturing the analyte (col. 2, lines 60-65, and col. 6, lines 29-24.) Pourahmadi also teaches that the device has a reservoir of magnetic beads functionalized with binding agents, wherein the magnetic beads may be vibrated or moved from one region to another using an electromagnetic field (col. 18, lines 40-50.) However, Pourahmadi et al. does not specifically teach that the magnetic beads are functionalized with antibody as the binding agent. Nelson et al. teaches this limitation.

Nelson et al. teaches a microfluidic device useful for such purposes as in vitro diagnostics, and for bioresearch generally (col. 2, line 65 – col. 3, line 2.) Nelson et al. teaches that the microfluidic device includes magnetic beads coated with antibodies for

capturing an analyte (col. 6, lines 30-45). Nelson et al. teaches that the magnetic particles may be retained in an enrichment channel by application of a magnetic field (col. 6, lines 43-45.) Nelson et al. teaches that not only can magnetic beads be used to move a sample, or capture or immobilize a magnetic bead-target complex during wash and elution steps, but a fluid sample can be flowed through channels within the device through a number of means or a combination of means, including active pumping means (col. 7, lines 8-19.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to coat the Pourahmadi et al. magnetic beads with antibodies as taught by Nelson et al. for diagnostic purposes because both Pourahmadi et al. and Nelson et al. teach that a magnetic field can be used to manipulate within a microfluidic device magnetic beads coated with affinity molecules to move the beads to a different part of the microfluidic device and Nelson et al. further teaches that magnetic beads coated with antibodies provide the advantage of binding to analytes for diagnostic or bioresearch purposes.

Response to Arguments

Applicant's arguments filed December 20, 2004 have been fully considered but they are not persuasive.

Applicant requests clarification as to how the passages in Pouramahdi et al. cited by Examiner would properly apply to the claimed fluid ports.

Examiner notes that a port is an opening. Thus, an opening in a compartment in the Pourahmadi et al. device is considered a port. The compartment (127) for example has at least two openings (see fig.) Pourahmadi et al. in column 9, lines 52-59, for example teaches that elution fluid may flow down channel (131), into compartment (127) and eventually through (41B) into another chamber (141). Thus, in this example, the opening leading into compartment (127) is the inlet port and the opening leading out of compartment (127) is the outlet port.

Applicant also argues that Pourahmadi also fails to teach that the discharge port is configured to emit a continuous flow of the biological fluid while the fluid receiving port receives the continuous flow of the biological fluid. The ports as described in the above paragraph are configured to emit and receive a continuous flow of biological fluid because they are capable of emitting and receiving a continuous flow of biological fluid passing through chamber (127.)

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641
3/17/05